

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

AUTO D-Dimer Calibrator, Cat. No. A7971

Sigma Diagnostics AUTO D-Dimer Calibrator is a human plasma control that is suitable for use as a calibrator in the Sigma Diagnostics AUTO D-dimer assay.

The safety and effectiveness of the Sigma Diagnostics AUTO D-Dimer Calibrator (Cat. No. A7971) has been demonstrated by its substantial equivalence to the Sigma Diagnostics AUTO D-Dimer Calibrator (Cat. No. A4842) marketed as part of the Sigma Diagnostics AUTO D-Dimer kit Procedure No. CRS126 (K003267).

Sigma Diagnostics AUTO D-Dimer Calibrator is a lyophilized human plasma based product. After reconstitution with water, AUTO D-Dimer Calibrator is stable for 3 days when stored at 2-8°C and 8 hours when stored at 18-26°C.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 26 2001

William R. Gilbert II, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics Inc.
545 South Ewing
St. Louis, MO 63103

Re: k013549
Trade/Device Name: Sigma Diagnostics AUTO D-Dimer Calibrator
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: DAP
Dated: October 10, 2001
Received: October 24, 2001

Dear Dr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013549Device Name: Sigma Diagnostics AUTO D-Dimer Calibrator**Indications For Use:**

Sigma Diagnostics AUTO D-Dimer Calibrator is a human plasma calibrator that is suitable for use as calibrator for the Sigma Diagnostics AUTO D-Dimer kit Procedure CRS126 for the quantitative determination of fibrin degradation products containing D-dimer in citrated human plasma in D-dimer agglutination assays.

Janette Mickie FOR: T. BAUTK71.
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013549

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____